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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,395	08/18/2004	Florian Lichtenberg	LP-1940	2442
217	7590	04/23/2007	EXAMINER	
FISHER, CHRISTEN & SABOL 1725 K STREET, N.W. SUITE 1108 WASHINGTON, DC 20006			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/23/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/501,395	LICHTENBERG ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Aradhana Sasan	1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 August 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-33 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/16/2004</u>	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Status of Application***

1. Claims 1-33 are being presented for examination.

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 11/16/2004 was filed.

The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98.

Accordingly, the examiner is considering the information disclosure statement. There are two dates missing from the references (notation made by examiner on PTO-1449). Appropriate correction is required.

See attached copy of PTO-1449.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11, and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

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protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 11, and 29-33 recite the broad recitation against parvoviruses or picornaviruses, and the claims also recite "in particular against polioviruses" which is the narrower statement of the range/limitation.

6. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-33 provide for the use of a disinfectant composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-33 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

To obviate these rejections, the claims should be amended to "method of use" claims. For example, a method of disinfecting surfaces, instruments etc. or a method of killing polioviruses.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-10, and 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCue et al. (US 5,908,854).

The claimed invention is the use of a disinfectant composition used as a virucidal agent. The disinfectant composition comprises (a) an amine (Ia) or a quaternary ammonium compound (Ib) and (b) at least one alkanolamine (II), in the mass ratio I:II of 20:1 to 1:20. The virucidal agent is used against parvoviruses or picornaviruses, particularly against polioviruses.

McCue teaches a composition effective against mycobacteria, and methods for using the composition (Abstract). The composition comprises about 0.1% wt. to about

25% wt. of a germicidal cationic quaternary compound, about 0.25% wt. to about 25% wt. of a solvent and water (Abstract).

Instant claim 1 recites limitations of the composition comprising (a) an amine (Ia) or quaternary ammonium salt (Ib) and (b) at least one alkanolamine of formula II. Substituents for the compounds are recited. McCue teaches quaternary ammonium compounds and salts thereof including quaternary ammonium germicides. The substituents ( $R_1$  to  $R_4$ ) of the quaternary ammonium compounds taught by McCue are hydrophobic, aliphatic, aryl aliphatic or aliphatic aryl radical of from 6 to 26 carbon atoms (Col. 2, lines 11-35). McCue teaches an alkanolamine compound, such as "mono-, di- or tri-ethanolamine" (Col. 4, lines 13-16). Although McCue does not specifically teach the mass ratio of quaternary ammonium compound to alkanolamine as 20:1 to 1:20, it would have been obvious to one skilled in the art to arrive at the claimed mass ratio during the process of routine experimentation to optimize the desired virucidal or disinfectant activity. Also, McCue teaches that many quaternary ammonium compositions "exhibit broad spectrum bactericidal, fungicidal and virucidal activity ..." (Col. 1, lines 11-16). Therefore, one skilled in the art would find it obvious that the instant invention would be effective as a virucidal agent.

Instant claim 2 recites an amine or quaternary ammonium salt selected from a group. McCue teaches didecyl dimethyl ammonium chloride (Col. 3, line 15-16). and would be obvious to one skilled in the art as a quaternary ammonium salt. Since the instant claims recite the composition comprising an amine and/or a quaternary ammonium salt, a person skilled in the art would find it obvious to recognize the didecyl

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dimethyl ammonium chloride taught by McCue as a quaternary ammonium salt (which is part of the instant composition).

The alkanolamine limitation of instant claims 3 and 12 would have been obvious to one of ordinary skill in the art over the McCue teaching of "an alkanolamine compound, particularly an ethanolamine such as mono-, di or tri-ethanolamine" (Col. 4, lines 13-16).

The mass ratio limitation of instant claims 4, 13, 14, and 15 would have been obvious to one of ordinary skill in the art over the McCue teaching of the germicidal composition and method of using it. One skilled in the art would vary the ratio of the quaternary ammonium compound and the alkanolamine in the process of routine experimentation in order to achieve the desired virucidal or disinfectant activity.

The limitation of water as a solvent for the disinfectant composition of instant claims 5, 16, 17, and 18 would have been obvious to one of ordinary skill in the art over the McCue teaching of "compositions ... dilutable in a larger volume of water" (Col. 4, lines 43-45).

The limitation of the composition comprising aids of instant claims 6, 19, and 20 would have been obvious to one of ordinary skill in the art over the McCue teaching of optional ingredients in the composition including "fragrances, surfactants, ... chelating agents, ..." (Col. 4, lines 23-26).

The limitation of surface disinfection and instrument disinfection of instant claims 7, 21, and 22 would have been obvious to one of ordinary skill in the art over the McCue teaching of using the compositions "in a wide variety of disinfecting applications, and in

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a wide variety of environments which may benefit from a disinfecting effect" (Col. 4, lines 51-53). McCue further teaches "disinfection of instruments and apparatuses, ... disinfection or decontamination of hospital environments including lavatories and lavatory fixtures, ..." (Col. 4, lines 55-64). Similarly, one with ordinary skill in the art would find it obvious to use the disinfectant composition of the instant application in laundry disinfection, hand disinfection, and in chemical toilets (limitations of instant claims 8-10 and 23-28).

9. Claims 11, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCue et al. (US 5,908,854), in view of Bellamy et al. (WO 94/22305).

The teaching of McCue is stated above.

McCue does not specifically teach the use of the composition against parvoviruses or picornaviruses or polioviruses.

Bellamy et al. teach an aqueous virucidal composition suitable as hospital disinfectant, comprising alkaline material and an alkyl quaternary nitrogen salt, effective for killing polioviruses and disinfecting heat sensitive medical instruments (Abstract).

Bellamy uses dialkyl dimethyl quaternary ammonium chloride as an example (Page 5, lines 15-17).

A person having ordinary skill in the art at the time the invention was made would have found it obvious to combine the use of the disinfectant composition taught by McCue with the virucidal (particularly against poliovirus) Bellamy composition. The motivation to combine these references is provided by Bellamy, which demonstrates the

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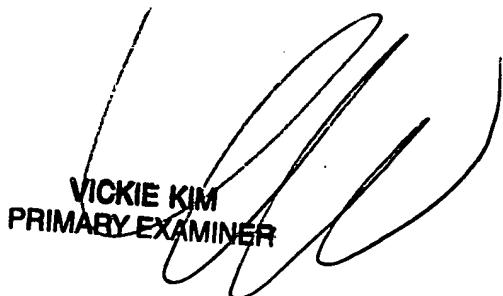
effectiveness of the anti-viral disinfectant composition, particularly against poliovirus  
(Page 8, lines 1-7).

***Conclusion***

1. No claims are allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
VICKIE KIM  
PRIMARY EXAMINER